2471 9/B
Box Seq

PATENT
Attorney Docket No. 3631-0117P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	KLYSNER, S. et al.	CONF #:	2471
SERIAL No.:	09/620,586	GROUP:	1644
FILED:	July 20, 2000	EXAMINER:	JAMROZ, MARGARET E.

FOR: METHOD FOR DOWN-REGULATING GDF-8 ACTIVITY

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

March 25, 2002

Sir:

In response to the Restriction Requirement of February 25, 2002, the following amendments and remarks are submitted in connection with the above-indicated application.

AMENDMENTS

In the Specification:

Please replace the last paragraph on page 25 (lines 25-33) with the following:

--One especially preferred PADRE peptide is the one having the amino acid sequence AKFVAAWTLKAAA (SEQ ID NO. 24) or an immunologically effective subsequence

thereof. This, and other epitopes having the same lack of MHC restriction are preferred T-cell epitopes which should be present in the GDF-8 analogues used in the inventive method. Such super-promiscuous epitopes will allow for the most simple embodiments of the invention wherein only one single modified GDF-8 is presented to the vaccinated animal's immune system.—

In the Claims:

1. (Amended) A method for *in vivo* down-regulation of growth differentiation factor 8 (GDF-8) activity in an animal, including a human being, the method comprising effecting presentation to the animal's immune system of an immunologically effective amount of
   - at least one GDF-8 polypeptide of subsequence thereof which has been formulated so that immunization of the animal with the GDF-8 polypeptide or subsequence thereof induces production of antibodies against the GDF-8 polypeptide, or
   - at least one GDF-8 analogue wherein the analogue has been modified so that at least one foreign T_H epitope moiety (A) is introduced such that immunization of the animal with the analogue induces production of antibodies against the GDF-8 polypeptide.

Please the following new claim:

53. (New) The method according to claim 1, wherein the GDF-8 analogue is introduced without a carrier molecule.

REMARKS

1. Sequence Listing

Applicant has corrected the mistake noted on page 25 of the Specification and hereby encloses both a paper copy and a disk containing a computer readable copy of

the Sequence Listing. Applicant hereby certifies that the content of the paper and computer readable copies are the same.

2. Restriction Requirement

Claims 1-52 are currently pending in the application. The Examiner has separated the claims into 94 different Groups and has required the Applicant to select a single invention for search and examination.

Applicant hereby elects the claims of Group I for prosecution, namely claims 1-23 and 29, drawn to a method for *in vivo* down-regulation of GDF-8 comprising administering at least one GDF-8 polypeptide, or fragment thereof OR at least one GDF-8 analogue wherein the analogue has been modified so that at least one foreign T_H epitope moeity (A) is introduced. The Examiner has also issued a Species election if the claims of Group I are elected. Applicant hereby elects Group I, i.e. a GDF-8 analogue wherein the analogue has been modified so that at least one foreign T_H epitope moeity (A) is introduced, and elects the species identified as <u>without a carrier molecule</u> for search and examination.

Claim 1 has been amended to relate to the elected invention. The remaining dependent claims 2-23 and 29 are also part of the same elected invention and should also be examined together. As alluded to by the Examiner, this election of species is only for purposes of initiating substantive examination. Once the elected species is found to be allowable, then examination must be broadened to other species encompassed by Applicant's generic claim.

Examination on the merits and favorable action on the claims in accordance with the above are requested.

If the Examiner has any questions concerning this application, he is requested to contact Leonard Svensson (Reg. No.: 30,330) the undersigned at (714) 708-8555 in the

Southern California area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By: _____

Leonard R. Svensson
Registration No. 30, 330

P.O. Box 747
Falls Church, VA 22040-0747
(714) 708-8555

LRS/KR

Attachment: Version to Show Changes Made
Sequence Listing (Paper and CRF)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner of Patents and Trademarks, Washington D.C. 20231 on: March 25, 2002
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Lori M Gilman
(Signature)

March 25, 2002
(Date of Signature)

Version to Show the Changes Made

In the Specification:

--One especially preferred PADRE peptide is the one having the amino acid sequence AKFVAAWTLKAAA (SEQ ID NO. 24) or an immunologically effective subsequence thereof. This, and other epitopes having the same lack of MHC restriction are preferred T-cell epitopes which should be present in the GDF-8 analogues used in the inventive method. Such super-promiscuous epitopes will allow for the most simple embodiments of the invention wherein only one single modified GDF-8 is presented to the vaccinated animal's immune system.—

In the Claims:

1. (Amended) A method for *in vivo* down-regulation of growth differentiation factor 8 (GDF-8) activity in an animal, including a human being, the method comprising effecting presentation to the animal's immune system of an immunologically effective amount of
   - at least one GDF-8 polypeptide of subsequence thereof which has been formulated so that immunization of the animal with the GDF-8 polypeptide or subsequence thereof induces production of antibodies against the GDF-8 polypeptide, [and/]or
   - at least one GDF-8 analogue wherein the analogue has been modified so that at least one foreign T_H epitope moiety (A) is introduced [at least one modification in the GDF-8 amino acid sequence which has as a result] such that immunization of the animal with the analogue induces production of antibodies against the GDF-8 polypeptide.